

Serial No.: 09/619,899  
Group Art Unit: 1616

### **Remarks**

This Amendment is responsive to the Office Action mailed October 16, 2003 (Paper No. 4). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Assuming entry of the amendments set forth in this Paper, the status of the claims is as follows:

<b>Amended:</b>	9, 26-30, 35, 48 and 50-51
<b>Cancelled:</b>	24 and 49
<b>New:</b>	52 and 53
<b>Pending:</b>	1-17, 19-48 and 50-52

### **Claims**

Claims 1-17 and 19-51 were pending. Claims 1-17 and 19-51 stand or stood rejected.

Claims 24 and 49 have been canceled without prejudice or disclaimer of the subject matter therein. Moreover, Applicant reserves the right to prosecute, in one or more patent applications, the canceled claims, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification.

Claims 9, 27-30, 35, 48 and 50-51 have been amended to more clearly define the invention and new claims 52 and 53 have been added which correspond to the claims previously numbered 24. No new matter is added.

It is believed that entry of this Amendment will not require payment of any additional claim fees. Notwithstanding, Applicant hereby authorizes the Commissioner to charge any additional claim fees deemed required by entry of this Amendment to Deposit Account No. 04-0480.

### **Support**

Support for the amendments to the claims is either apparent or as set forth herein. Support for the recitation "by weight" may be found throughout the specification, for example, see paragraph number [0055] and the Examples. Support for the recitation "wherein the polymer exhibits dissolution properties that are different from those of the hydrocolloid" may be found in the specification at, for example, paragraph number [0012]. No new matter is added.

**Specification**

Claims 9, 24, 26, 30, 35, 48 and 49 stand or stood rejected as informal. Specifically, the Examiners asserts that

Claims 9, 35, line 2 of each, “polysaccharade” should be “polysaccharide”.

Claim 30, line 10, “dissolution time on” should be “dissolution time of”.

Claim 48, line 1 “dissintegration” should be “disintegration”.

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or requote the claim(s) in independent form.

Claim 30 on which Claim 49 dependent already contains a limitation in which the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid.

\* \* \*

**There are two claims numbered 24 and claim 26 is dependent on claim 24.**

Applicants have amended claims 9, 30, 35 and 48 to correct the spelling errors noted by the Examiner. Applicants have cancelled claim 24 and entered new claims 52 and 53 corresponding to the previous claims numbered 24. Applicants have cancelled claim 49 without prejudice or disclaimer of the subject matter contained therein. Reconsideration and withdrawal of these objections to the claims are respectfully requested.

The disclosure stands objected to as informal. Specifically, the Examiner asserts that

Pg. 25, lines 1, 2, “Sildanedil” should be “Sildenafil”,  
“Sildanefil” should be “Sildenafil”.

Pg. 6, line 15, Figure 6 and Pg. 25, line 2, “Viarga” should  
be followed by “®”.

Applicants have amended Table 11 on page 25 and paragraph [0017] of the disclosure to obviate the asserted bases for these objections. Reconsideration and withdrawal of these objections are respectfully requested.

The specification stands objected to as not providing proper antecedent basis for the claimed subject matter. Specifically, the Examiner asserts that

Claims 27, 30, 49 recite a limitation wherein the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid. However, the specification does not appear to contain this limitation and mentions encapsulation only in relation to dissolution properties (See Specification, pg. 4, lines 9, 10, pg. 9, lines 5-8).

Applicant respectfully disagrees. Applicant directs the Examiner's attention to paragraph numbers [0012], [0025] and [0053] which read, in relevant part, as follows:

[0012] In an embodiment of the invention, the hydrocolloid includes a polymer selected from the group consisting of a natural, semi-natural and synthetic biopolymer being exemplified by a polysaccharide and a polypeptide....**The active agent may be encapsulated within a second polymer having dissolution properties that are different from those of the hydrocolloid....**

[0025] Embodiments of the invention provide a delivery system for active agents and other active agents that will dissolve and completely release their contents on a moist mucosal surface for example in the oral cavity. ...**For these applications, the active agent may be encapsulated in a material with dissolution properties that are different from those of the hydrocolloid....**

[0053] In an embodiment of the invention, a water soluble polymer (2% polymer solution) is selected having a gelation temperature greater than 70°C. ...**The active agent in the film may be encapsulated in a polymer having different chemical or physical properties from the hydrocolloid of the film and having dissolution properties different from those of the hydrocolloid....**

(emphasis added). Reconsideration and withdrawal of this objection to the specification are respectfully requested.

#### **Claim Rejections under 35 U.S.C. §112 Second Paragraph**

Claims 1-17 and 19-51 stand or stood rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Examiner asserts that

[c]laims 1-17, 20-43, 45-51 contain the phrase "effective dose of a sexual dysfunction active agent", however, the Specification (other than sildenafil citrate) does not appear to define what would constitute a sexual dysfunction active agent or effective dose thereof. As such, it does not appear that one of ordinary skill in the art would be reasonably apprised of the scope of the invention.

Applicant respectfully disagrees. Those skilled in the art know what the term “sexual dysfunction active agent” entails and what an effective dose would comprise. One skilled in the art would know to look to the Physicians Desk Reference to find such information.

Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner further asserts that

Claims 7, 33 recite the phrase “a hydration rate in 24 hours of 5-20% at 75% humidity at room temperature” which renders the claim indefinite as it is uncertain what the percent relates to.

Applicant respectfully disagrees. Applicant respectfully notes that one skilled in the art would recognise that the 5-20% refers to the increase in mass percent of the substance due to water absorption from the surrounding atmosphere having a 75% relative humidity. Reconsideration and withdrawal of this objection to the specification are respectfully requested.

The Examiner further asserts that

Claims 28, 50 recite the phrase “wherein the dosage unit comprises at least two active agents” which lacks antecedent basis as the independent claim appears to indicate that the composition contains a single sexual dysfunction active agent.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner further asserts that

Claims 29, 51 recite the phrase “concentration of up to 50%” which renders the claims indefinite as there are no units, i.e. volume or mass.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner further asserts that

Claims 27, 30, 49 recite a limitation wherein the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid. However, the specification does not appear to define what would constitute “chemically or physically distinct” and mentions encapsulation only in relation to dissolution properties (See Specification, pg. 4, lines 9,10, pg. 9, lines 5-8). As such, it appears that one of

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ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner further notes as follows:

Examiner notes that the measurement of the properties of the film is based on protocols which are described in the Annual Book of ASTM Standards (1995) and "Dry tack" is measured using Texture analyzers, model TA.XT2i. Examiner is uncertain whether these tests or protocols are recognizable commercial standards or otherwise can be standardized such that one of ordinary skill in the art would be able to determine the scope of the claims herein. As such, Examiner requests copies of the relevant ASTM and relevant manufacturer's specs of the Texture Analyzer, model TZ.XT2i, such that they may be readily available should the present Application be issued as a patent.

Applicants respectfully disagree. The subject documents are readily available to the public. One skilled in the art would know that the subject documents are available from ASTM International, *inter alia*, on their website at "www.astm.org" where these documents may be viewed free of charge.

### **Double Patenting**

Claims 1-17 and 19-51 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over the claims of copending Application No. 09/434,878. Without conceding the validity of this provisional rejection, Applicants have elected to submit a terminal disclaimer. Reconsideration and withdrawal of this provisional rejection are respectfully requested.

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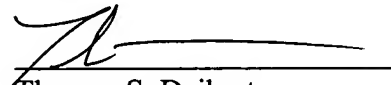
**FEE DEFICIENCY**

- ☒ If an additional extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.
- and/or**
- ☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

**Closing Remarks**

Applicant thanks the Examiner for the Office Action and believes this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

  
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